

### **REMARKS**

In the Office Action dated June 16, 2008, claims 1, 8-22 and 29-32 were examined with the result that all claims were rejected. In response, Applicant has cancelled claims 31 and 32, amended claims 1 and 29, and added new claims 33-45 via the present Amendment. In view of the above claim amendments and following remarks, reconsideration of this application is requested.

Before turning to the rejections of record, Applicant would like to briefly summarize the amendments made to the claims via the present Amendment. More specifically, claim 1 has been amended to now recite a method of stimulating growth of new periodontal bone in a mammal comprising administering to the mammal a therapeutically effective amount of a compound of the described formula. Thus, claim 1 has now been limited to stimulating growth of new periodontal bone, and presents no new matter issue as this use was set forth in original claim 27 as filed.

Claim 29 has been amended herein to call for a method of stimulating osseointegration of a dental implant in a mammal, comprising administering to the mammal a therapeutically effective amount of a compound as described therein. Thus, claim 29 has been limited to stimulating osseointegration of a dental implant, and presents no new matter issue as this use was set forth in original claim 26 as filed. In addition, Applicant has added new claims 33-45 which correspond substantially with original claims 8-9 and 11-21, except depending from independent claim 29.

In the Office Action, claims 1, 8-22 and 29-32 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1, 8-10, 20 and 29-38 of co-pending application no. 10/105,826 in view of Bockman et al U.S. 5,556,645. This rejection is a provisional rejection because the allegedly conflicting claims in the two applications have not in fact yet been patented. The Applicants respectfully traverse the rejection in view of the foregoing claim amendments, and for the following reasons.

The present claims relate to methods of stimulating growth of new periodontal bone (claim 1) and methods of stimulating osseointegration of a dental implant (claim 29). In

contrast, the claims in co-pending application no 10/105,826 relate to methods of "increasing the rate of repair for a bone fracture." The difference between the present claims and the claims of the co-pending application is that that the co-pending application is directed toward repair of bone fractures, whereas the present application is directed toward forming new periodontal bone and osseointegration of dental implants. These are completely unrelated uses, and one skilled in the art would not turn to references referring to bone fracture healing for a teaching regarding osseointegration of a dental implant and/or growth of new periodontal bone. The claims are directed toward different therapeutic uses, and are not obvious variations of each other. Further, although Bockman et al U.S. 5,556,645 may teach that osteoblasts are responsible for regulating the rate of bone formation, it never mentions or discusses in any way dental implants and/or the formation of periodontal bone. Thus, Applicant believes the differences between the instant claims and the claims of the co-pending application are materially different, and requests the Examiner withdraw the obviousness type double patenting rejection.

In the Office Action, claims 1, 8-22 and 29-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca et al U.S. 5,843,928 in view of DeLuca et al WO 02/05823 and Bockman et al U.S. 5,556,645. The Examiner's basic position is that Applicant's previous remarks in the response of February 21, 2008 argued a mechanism of action, i.e. stimulating osteoblasts, and this mechanism did not alter the fact that the claimed compounds had been previously used to obtain the same pharmacological effects. Further, the Examiner indicated that the "patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims." Applicants, however, respectfully traverse the rejection in view of the foregoing claim amendments and for the following reasons.

The DeLuca et al '928 patent cited by the Examiner teaches that the compound 2MD (which is covered by the structural formula of claims 1 and 29), may be used for the treatment of metabolic bone diseases where bone loss is a major concern, such as osteoporosis. The '928 patent also teaches that the compound 2MD is suitable for improving

bone fracture healing and improved bone grafts. However, nowhere does the '928 reference teach and/or suggest that 2MD is useful to stimulate growth of new periodontal bone or to stimulate osseointegration of a dental implant. Such claimed uses are a far cry from osteoporosis, bone fractures and bone grafts.

DeLuca et al WO '823 teaches that 2MD stimulates osteoblasts in a manner more potent than the native hormone, namely,  $1\alpha,25$ -dihydroxyvitamin  $D_3$  and is thus useful in hip and knee replacement surgery. Again, this is a far cry from stimulating the formation of new periodontal bone and/or stimulating the osseointegration of a dental implant.

DeLuca et al WO '823 also teaches that the compound 2MD not only has an anabolic effect on bone, but also increases bone strength. However, all of the data contained in WO '823 relates to increased strength in femur bone and/or vertebrae. Again, there is nothing in WO '823 that teaches or suggests the use of 2MD to stimulate the growth of new periodontal bone and/or to stimulate the osseointegration of a dental implant.

Accordingly, Applicant requests the Examiner withdraw the §103(a) rejection of the claims. The references cited by the Examiner, either individually or in combination, do not teach or suggest the claimed therapeutic uses.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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